

Appl. No. : 09/916,711
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REMARKS

Claims 1-10, 12-15, 21-28, and 30-33 are pending in this application. Claims 1, 2, and 25-28 have been amended. Support for the amendments to Claims 1, 2, and 25-28 is found, e.g., in Figure 9 and paragraph [0119] of the specification as filed.

Claim Rejection - 35 U.S.C. § 103(a) – Shults et al. in view of McIvor et al.

Claims 1, 2, 5-10, 12-15, and 22-33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. 6,001,067 (“Shults et al.”) in view of U.S. 6,360,888 (“McIvor et al.”). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). There is no such suggestion or teaching, and, in fact, the disclosures teach away from the invention as recited in the pending independent claims, which recite, *inter alia*, a wholly implantable analyte measuring device “wherein said electrochemical reactive surface of said counter electrode is greater than or equal to about six times the surface area of said working electrode.” *A prima facie* case of obviousness cannot be established if the disclosure of the cited prior art, when taken as a whole, teaches away from the claimed invention. *See, e.g.*, M.P.E.P. § 2141.02.

It is asserted that it would have been obvious to modify the glucose sensing device of Shults et al., wherein the working and counter electrodes having the same surface area, to include the electrode system of McIvor et al, wherein the counter electrode is larger than the working electrode, as merely the substitution of one known equivalent structure for another. Applicants respectfully disagree. Shults et al. is directed to a wholly implantable glucose sensor wherein the electrode and membrane structure are integrally formed on the body that is adapted to be wholly implanted into a host for long term glucose sensing. In contrast to Shults et al., the sensor of McIvor et al. is a transcutaneous sensor. As known to those of skill in the art (and as is evident from limits on FDA approved usages of transcutaneous glucose sensors), transcutaneous sensors, such as the sensor of McIvor et al., are only suitable for short term use, e.g., 72 hours or less. The sensor of McIvor et al. is only suitable for short term use because it does not include a cell disruptive domain as in the sensors recited in the pending claims. Accordingly, cells will grow on and around the sensor and form a foreign body capsule, causing such a sensor to lose function

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after a few days. While McIvor et al. teaches “optimizing the size, shape and orientation of the glucose sensor electrodes” of the transcutaneous sensor, such optimization would not necessarily result in a wholly implantable sensor system capable of providing accurate readings in an oxygen deficit. Therefore, the substitution of the structure of the McIvor et al. glucose sensor into the Shults et al. glucose sensor would not necessarily produce a sensor unsuitable for its intended use, namely a wholly implantable sensor capable of operating in an oxygen deficit. Accordingly, there is no motivation to combine.

Moreover, evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987; *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Referring to Figure 9 of the application as filed, as discussed in paragraphs [0117] to [0119], comparative data is presented for a sensor wherein the working and counter electrodes are the same size and for sensors wherein the counter electrode is six times as large as the working electrode. The figure clearly demonstrates that the large Pt and Au counter electrode devices do not begin to reach the circuitry limits at low oxygen concentrations, as does the device wherein the electrodes are the same size, and thus a 6× larger counter electrode configuration, as recited in Claims 1 and 2 (and also in Claims 30 and 32, which recite the device of Claim 1), unexpectedly provides increased performance and accuracy necessary in a wholly implantable sensor which is subject to oxygen deficit conditions. It is also noted that McIvor et al. does not teach an analyte measuring device that further comprises an enzyme domain configured for long-term use, wherein said enzyme domain covers said working electrode and said counter electrode. Moreover, without the unexpected results noted by Applicants, there would be no motivation to spend the extra money to increase the size of the counter electrode of Shults because the platinum used in the electrode is very expensive. Absent the unexpected results, one skilled in the art would be motivated to reduce the size of the counter electrode to save on materials costs.

Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) – Shults et al. in view of McIvor et al. and further in view of Schulman et al.

Claims 3 and 4 have been rejected under 35 U.S.C. §103(a) as obvious over Shults et al. in view of McIvor et al., in further view of U.S. 6,119,028 (“Schulman et al.”). As discussed above, pending independent Claims 1 and 2, from which Claims 3 and 4, respectively, depend,

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are not obvious over Shults et al. in view of McIvor et al. Schulman et al. does not overcome the deficiencies of Shults et al. and McIvor et al.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 103(a) –Shults et al. in view of McIvor et al. and further in view of Ward et al.

Claim 21 has been rejected under 35 U.S.C. §103(a) as obvious over Heller et al., Shults et al., and McIvor et al., in further view of U.S. 6,119,028 ("Ward et al."). As discussed above, pending independent Claim 2, from which Claim 21 depends, is not obvious over Shults et al. in view of McIvor et al. Ward et al. does not overcome the deficiencies of Shults et al. and McIvor et al.

Accordingly, Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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